

SYNTREG

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H0: The effect of product A is equal to the effect of product B with respect to change from baseline after 8 weeks of study product intake in IL-10 production [pg/mL] AND in Foxp3 expressing cells. H1: The effect of product A is unequal to the...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22553

Bron

Nationaal Trial Register

Verkorte titel

SYNTREG

Aandoening

Immune modulatory activity of a pre-probiotic blend in healthy adult volunteers

Ondersteuning

Primaire sponsor: Nutricia Research BV

Overige ondersteuning: Nutricia Research BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change from baseline in IL-10 production and/or forkhead box protein 3 (Foxp3) expressing cells after 8 weeks of daily study product intake.

Toelichting onderzoek

Achtergrond van het onderzoek

Not yet available

Doel van het onderzoek

H0: The effect of product A is equal to the effect of product B with respect to change from baseline after 8 weeks of study product intake in IL-10 production [pg/mL] AND in Foxp3 expressing cells.

H1: The effect of product A is unequal to the effect of product B with respect to change from baseline after 8 weeks of study product intake in IL-10 production [pg/mL] OR in Foxp3 expressing cells.

Onderzoeksopzet

V1 (Day 1); V2 (Day 14); V3 (Day 56)

Onderzoeksproduct en/of interventie

Duration of intervention: 8 weeks

Intervention group: A pre-probiotic blend and maltodextrose

Control group: maltodextrose

Contactpersonen

Publiek

Nutricia Research B.V.

Monique Visser
PO Box 80141

Utrecht 3508 TC
The Netherlands
+31-30-2095000

Wetenschappelijk

Nutricia Research B.V.

Monique Visser
PO Box 80141

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The Netherlands
+31-30-2095000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 18 and ≤ 40 years
- Written informed consent
- Willingness and ability to comply with the study protocol
- Body Mass Index (BMI) ≥ 18.5 and ≤ 24.9 kg/m²
- Non-smoking or stopped smoking for at least 3 months prior to Visit 1 (randomisation)
- Regular stool (stool frequency of at least 1 stool in 3 days)
- Judged by the investigator to be in good health

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Any medical condition that interferes with GI function (e.g irritable bowel syndrome, short bowel syndrome, inflammatory bowel disease, gastric ulcer, gastritis (gastro)enteritis)
- Constipation and/or diarrhoea within 1 week prior to Visit 1 (randomisation)
- Any known allergy and/or intolerance (e.g. coeliac disease, gluten intolerance, allergy to one of the ingredients of the study product)
- Any known renal or hepatic failure

- (History of) any immunological disease and/ or immunodeficiency
- (History of) any cancer with the exception of basal cell carcinoma
- Use of prokinetics, laxatives, antidiarrhoeals, corticosteroids, proton-pump inhibitors (or other gastric acid reducers), immunosuppressants or any active allergy treatment within 3 weeks of Visit 1 (randomisation)
- (History of) any chemotherapy or immunotherapy
- Use of antibiotics within 3 months of screening

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	21-02-2017
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	14-02-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6095
NTR-old	NTR6242
Ander register	Stichting BEBO : 15AL89652

Resultaten

Samenvatting resultaten

No